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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/789,441	02/21/2001	Masahiko Matsukata	791_135	7284

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BURR & BROWN
PO BOX 7068
SYRACUSE, NY 13261-7068

EXAMINER

MENON, KRISHNAN S

ART UNIT PAPER NUMBER

1723

DATE MAILED: 10/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/766,161	COLMAN, MICHAEL S.	
	Examiner	Art Unit	
	Krishnan S Menon	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as originally filed does not support the elements “..providing an ultrafiltration membrane having a predetermined molecular weight limit..” and “..said nucleic acids comprise nucleic acids having a molecular weight below said predetermined molecular weight limit of said membrane..” in para 2 and 3 of this claim.

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 14 recites “..providing an ultrafiltration membrane having a predetermined molecular weight limit..” and “..said nucleic acids comprise nucleic acids having a molecular weight below said predetermined molecular weight limit of said membrane..” in para 2 and 3. The specification does not disclose the molecular weight cut-off limits of the membrane to support these elements in the claim.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 9,11,14,15,17 and 19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Schneider (US 5,596,092).

Schneider (092) discloses a process for the recovery/fractionation of nucleic acids contained in a liquid comprising dilution and then ultrafiltration through a membrane to dryness (col 4 lines 42-54) as in instant claims 1, 14 and 17. The dilution is about 4 fold of its initial concentration as in instant claims 2 and 15 (NaCl strength brought from about 2M to below 0.5M: lines 13-16 col 2, and line 44 col 4). Dilution by water as in instant claims 3 and 19, and it is DNA as in instant claim 4 (col 4 lines 42-54).

Schneider (092) teaches fractionation of the liquid samples by increasing the concentration by addition of quaternary ammonium salt as in instant claims 9 and 11 (col 3 lines 1-5).

Schneider (092) teaches dilution to bring the NaCl concentration to less than 0.5M, without providing a reason for the dilution, before ultrafiltering through a glass filter of 10-16 micron pore size (col 3 lines 5-16). Nevertheless, since Schneider (092) uses a filter of significantly large pores compared to the size of the DNA molecules and dilutes the sample to make the ultrafiltration of the DNA possible, instant claims 14 and 17 are anticipated by Schneider (092).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 5-8,12,16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider (092).

Schneider (092) discloses a process for the recovery/fractionation of nucleic acids contained in a liquid comprising dilution and then ultrafiltration through a membrane to dryness (col 4 lines 42-54) as in instant claims 1, 14 and 17. Schneider (092) is silent on the vacuum pressure applied for ultrafiltration as in instant claims 5-8 and 12. However, it is well known in the art to apply a relatively constant vacuum pressure for ultrafiltration using a dead-end filter and the vacuum pressure applied is based on convenience of how quickly the filtration be completed. Schneider (092) is silent on the size of the DNA fragments recovered, but does state good recovery with the borosilicate sintered glass ultrafilters (col 3 lines 5-16). It would be obvious to one of ordinary skill in the art at the time of invention to use the Schneider (092) process of dilution and ultrafiltration to make complete recovery of the DNA using a Millipore multi-screen plate filter as alternate but equivalent filter.

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2. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider (092) in view of Simon (US 5,434,048).

Schneider (092) does not teach use of nucleic acid condensing agents like Mg etc. for fraction recovery of such nucleic acids. Simon (048) teaches use of monovalent and bivalent cations like KCl and MgCl₂ (col 5 lines 28-34) in centrifugal ultrafiltration. It would be obvious to one of ordinary skill in the art at the time of invention to use the bivalent cations from the teachings of Simon (048) in the teachings of Schneider (092) for improved fractionation of the contaminants.

3. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider (092) in view of Bussey (US 6,011,148).

Filtering with a second pressure is only a repeat process of filtering with the first pressure. Schneider (092) does not teach filtering at different pressures for recovering DNA fragments of different sizes. Bussey (148) teaches that "Generally filtration process is faster with higher pressures, but higher pressures are likely to cause shearing of the nucleic acid or loss due to passage through the membrane" (lines 30-40, col 7). This statement proves that lower trans-membrane pressures would afford recovery of lower nucleic acid fragments. Therefore, it is obvious for one of ordinary skill in the art at the time of the invention that flow through an ultrafiltration membrane is pressure dependent and one could subject the samples to different pressures to obtain different flow rates of each species. It is also obvious to one ordinarily skilled in the art at the time of invention that filtering a second time with a different pressure would result in better recovery.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S Menon whose telephone number is 703-305-5999. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L Walker can be reached on 703-308-0457. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Krishnan S. Menon
Patent Examiner
October 9, 2002


W. L. WALKER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700

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Colman **09/766.161** **1/19/2001**

Claim #	Claim limitations	Geiger: 12/96	Bussey: 1/2000	Simon 7/95
1	selective recovery of nucleic acids from liquids	Abs, 3(31-46)	Abs, 2(55-67)	
	diluting liquid	6(27-41) hybridization solutions is obvious for dilution;, 10(1-28) washing solution in mmb obvious as dilution	4(10-24)	
	ultrafiltration membrane	3(31-46)	4(45-54)	
	Liquid -> pressure differential		3(6-10)	
2	1+ Dilution 1/3 to 1/5 of initial	10(1-28) the number of washes amount to this dilution range	4(10-24)	
3	1+ Diluent: selected from..consisting of.. water/ edta/trishydrochloride/trisEDTA	6(27-41) contains water and EDTA	10(5-20), 11(45-55)	
4	1+ double stranded DNA or RNA	Abs, 7(12-37), 4(23-34)	3(24-32) doble stranded obvious from concn of ss DNA	
5	1+ constant pressure differential		7(28-32)	
6	Selective recovery of Nac	3(31-46)	Abs, 2(55-67)	
	UF membrane with up and down streams	3(31-46)	4(44-55)	
	Pressure differential <25" Hg		7(35-43)	
7	6 + 10" Hg		7(35-43)	
8	6+ constant pressure diff		7(28-32)	
9	Selective removal of contaminants	3(31-46)	2(55-67), abs	

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	Increase conc by adding condensing agents/ mono cations			5(28-34), 7(35-39)
	UF mmb		4(44-55)	
	Diff. Pres		7(35-43)	
10	9+Select from grp consisting of Mn, Mg, 6Am-CoCl, Permine, spermadine, or mix			5(28-34), 7(35-39)
11	9+Mon ats – Na, K, NH ₄		10(5-20)	
12	9+Const pr.		7(28-32)	
13	Selective recovery of linear Nac			
	Dilution			
	UF mmmb			
	First pr			
	Second pr		Obvious	